October 14, 2002

Christine Todd Whitman, Administrator
U. S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: Comments on the Pine Chemicals Association, Inc.'s HPV Test Plan for Rosin Esters

Dear Administrator Whitman:

The following comments on the Pine Chemicals Association, Inc.'s (PCA) test plan for rosin esters are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The PCA includes such well-known chemical companies as Eastman Chemical Co. and Akzo Nobel and it has repeatedly submitted thoughtless test plans that call for extensive animal testing. This particular test plan demonstrates a blatant disregard for the minimal animal welfare principles outlined in the October 1999 agreement among the EPA, industry, and health, animal protection, and environmental organizations, as well as the December 2000 *Federal Register* notice reconfirming that agreement. As currently planned, the PCA test plan will kill approximately 1,300 animals in completely unnecessary testing.

This current test plan violates the following terms of the October 1999 Agreement:

2. Participants shall maximize the use of existing and scientifically adequate data to minimize further testing.

3. Participants shall maximize the use of scientifically appropriate categories of related chemicals and structure activity relationships.

Rosins are naturally occurring substances found in pine trees and used commercially for printing inks, adhesives, chewing gums, coatings, soaps, and detergents. The Rosin Esters category is closely related to the Rosins and the Rosin Adduct and Adduct Salts categories, consisting of rosins that have been chemically reacted with alcohols or polyols to form esters. These substances are used primarily as adhesives. The substances in this category are all relatively non-toxic, with no observed effects at doses of 1000 mg/kg/day for any data of the existing endpoints.

The PCA is proposing to conduct a full SIDS battery on one member of the category, and additional testing on a second member, despite the fact that there are existing data for all SIDS endpoints. The proposed battery includes an acute oral toxicity test, a OECD 422 combined repeat dose/reproductive/developmental toxicity test for one member, a developmental study for one member (the PCA lists this as the OECD 421, although the developmental toxicity study is the OECD 414), and an OECD 203 acute fish toxicity test for two members. As stated above, these tests as listed will kill approximately 1,300 animals. If the OECD 414 is used, the number rises to approximately 2,600.

Any additional animal testing whatsoever with rosins esters is inappropriate. The PCA has already proposed testing of similar chemicals in the previous test plan for rosins and rosin salts and rosin adducts and rosin adduct salts. The PCA should have included these substances in a larger rosins category. All these chemicals are closely related and are substances with high molecular weight, low solubility, and high Kow, indicating that they should exhibit similar behaviors. An expansion of the category would provide greater insight into the relationship between structure and toxicity and, importantly,

would reduce the numbers of animals killed in this HPV testing.

Existing data for all compounds in this category already show that these compounds have a low toxicity, with no acute toxicity observed at 2000 mg/kg/day for one member of the group, and no observed effects at doses less than 1000 mg/kg/day for reproductive, genotoxicity, and repeat dose testing. Existing data already show that two-year reproductive testing and 90 day studies at 1000 mg/kg show no adverse effects. It is obvious that, with no observed effects at 1000 mg/kg/day for other endpoints conducted in long term tests, developmental toxicity is not an issue, especially when one considers the existing data from other compounds that should be in the group (rosins and rosin adducts and salts).

Once again, we also urge the PCA to replace the proposed acute fish toxicity tests with other methods, such as ECOSAR or Tetratox. The PCA is, yet again, proposing irrelevant aquatic toxicity tests on fish. Testing rosin esters on fish is especially inappropriate because its insolubility in water and lack of hydrolyzable functional groups hinder the ability to conduct aquatic tests and indicate that this chemical is unlikely to be bioavailable to aquatic life. The PCA acknowledges the limitations of testing rosin-derived substances in aquatic environments and therefore proposes to manipulate experimental conditions, which may confound the results.

We have had repeated contact with the PCA regarding previously submitted test plans that call for mammalian acute toxicity testing. The PCA has so far refused to conduct the EPA-recommended *in vitro* cytotoxicity testing prior to conducting the *in vivo* testing, even on known non-toxic materials. If the EPA guidance on the use of the *in vitro* cytotoxicity test is to have any credibility, the EPA must pursue this matter directly with the PCA.

In summary, none of the animal tests proposed by the PCA is appropriate. This test plan is particularly egregious and the EPA must reject it. Thank you for your attention to these comments I can be reached at 757-622-7382, ext.1304, or via e-mail at jessicas@peta.org.

Sincerely,

Jessica Sandler
Federal Agency Liaison